

cumstances to assist the Agency's determination of device safety and effectiveness. One example is left ventricular assist device (LVAD) therapy for end-stage heart failure. **METHODS:** Clinical trials conducted in support of LVAD regulatory approval have demonstrated mortality benefits compared to optimal medical therapy alone. However, significant adverse events are also typically observed, including sepsis, bleeding and stroke. The regulatory challenge is to determine an acceptable tradeoff between mortality and adverse events. In this regard, PRO's including quality of life measures could provide additional information to assist in decision-making for device approval and also guide development of a more informative product label. **RESULTS:** Three issues need to be addressed to boost the scientific validity of PRO's in heart failure device trials: 1) the inherent unblinded study design for such devices makes PRO's susceptible to patient bias, confounding study results; 2) differential rates of follow-up between treatment arms: patients too moribund to complete follow-up assessment tools might lead to underreporting of negative HRQOL data and confound study results; and 3) a consensus needs to be achieved regarding the selection of valid assessment tools for heart failure studies. **CONCLUSIONS:** PRO's have promise in heart failure device evaluation, however, several important issues need to be addressed to properly incorporate such measures in studies intended for regulatory approval. The FDA welcomes dialogue with the clinical, academic and industry communities to develop appropriate PRO measures for heart failure device therapy.

**PHP39****SELF-EFFICACY AND ACADEMIC ACHIEVEMENT OF THE FIFTH YEAR PHARMACY STUDENTS OF CHULALONGKORN UNIVERSITY, 2003**

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**OBJECTIVES:** To predict students' academic achievement (GPA) by Self-efficacy (SE). SE is defined as the self-perception that one can master a certain task or perform adequately in a given situation. **METHODS:** A descriptive cross-sectional survey was employed for studying the relationship between Self-efficacy and academic achievement (GPA) of all (178) 5th year pharmacy students at The College of Pharmacy, Chulalongkorn University, Bangkok, Thailand during the period of August to September, 2003. **RESULTS:** The final return rate of questionnaire was 171 (96.06%). The respondents average age was 22.02 years. Most (124) were female (72.51%). The reliability coefficient (Cronbach's alpha) of Self-Efficacy (SE) scale was 0.87. The findings showed that there was positive relationship between SE and academic achievement (GPA)  $r = 0.38$  ( $p = 0.03$ ). The length of time for preparing for an examination by a female was longer than for a male ( $p = 0.03$ ). There was no difference between male and female SE ( $p = 0.07$ ). However, female's GPA was significantly higher than male's ( $p = 0.02$ ). SE of the Bangkok students was not different from the Non-Bangkok students ( $p = 0.87$ ). Students who participated in activities had higher SE than students who did not ( $p = 0.24$ ) but the GPA of the two groups was not different ( $p = 0.59$ ). Attitude toward pharmacy profession had no impact on SE nor GPA ( $p = 0.78, 0.82$ ). The three predictors of the model were SE, Gender, and Time (to prepare the examination)  $R^2 = 0.40$ ,  $\beta = 0.38, 0.10$ , and  $0.07$  ( $p = 0.02$ ). IQ was not controlled in this study. **CONCLUSIONS:** Self-Efficacy was a good predictor of academic achievement of Chulalongkorn University, pharmacy student class of 2003.

**OBESITY****OBESITY—Cost Studies****POB1****OBESITY AND THE RISK OF UPPER RESPIRATORY TRACT INFECTIONS**

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**OBJECTIVES:** High Body Mass Index (BMI) and obesity, prevalent throughout industrialised societies, are known to be associated with many co-morbidities. A possible increase in upper respiratory tract infections (URTI) associated with higher BMI was investigated in this study. **METHODS:** Cohort study using prospectively recorded patient data within the Full Feature General Practice Research Database (GPRD) which represents approximately 5% of UK population. Study subjects were categorised according to their baseline BMI into five exposure groups: I 18.5–24.9; II 25.0–29.9; III 30.0–34.9; IV 35.0–39.9 and V 40.0 and above. BMI records of 50.0 and over were discarded. Patients were followed from January 1, 1998 until December 31, 2002. Study outcomes were either Ear Nose and Throat (ENT) infections, or Respiratory Tract Infections (RTI). Statistical analysis: For each outcome group, crude incidence rates and incidence rate ratios (IRR) by BMI category were estimated. Poisson regression analysis was used to make adjustments for age, gender, asthma, COPD, diabetes, smoking status, GP consultations and sleep apnoea. **RESULTS:** A total of 244,479 patients were eligible for the cohort. The adjusted IRR for ENT infections and URTI respectively was for BMI group II, 1.13 (1.11, 1.15) and 1.10 (1.08, 1.12), for BMI group III, 1.18 (1.15, 1.21) and 1.21 (1.17, 1.24) BMI group IV, 1.23 (1.17, 1.28) and 1.33 (1.27, 1.39) and for BMI group V 1.29 (1.20, 1.38) and 1.42 (1.32, 1.53). These findings were consistent after stratification by the number of GP consultations in 1997. **CONCLUSIONS:** This study provides evidence that there is an association between increasing BMI and ENT and upper respiratory tract infection. This association should be taken into consideration in the evaluation of the burden of obesity.

**POB2****SOCIAL COST OF OVERWEIGHT AND OBESITY:****SPESA STUDY**

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**OBJECTIVE:** In Italy, the most recent report for the National Institute of Statistics (ISTAT) indicate that 1/3 of Italians are overweight and 1/10 obese, making the problem less dramatic than in the UK, Germany or USA. The objectives of this prospective naturalistic study were to describe direct and indirect costs attributable to the management of overweight and obesity and to identify factors associated with costs of management of subjects with overweight and obese. **METHODS:** The study included subjects between 18–65 years old with a body mass index greater than 25 (BMI, defined as weight in kilograms divided by the square of height in meters). Our estimates of the direct Health Care costs for the Italian National Health Care Service (I-Nhs) refer to 399 subjects enrolled at 52 centers and show a significant increase in total and I-Nhs monthly costs with increasing BMI. **RESULTS:** The increase in the average total monthly costs between overweight (82€), mild (189€), moderate (197€) and severe (233€) obese subjects was borderline significant ( $P = 0.051$ , Kruskal Wallis test). The increase in the average